



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

~~8-15-88~~
June 30 1988

#23

In re Purdue Research)
Foundation)
) 35 U.S.C. 156

An application for patent term extension of U.S. Patent 4,543,954 was filed on June 27, 1988, under 35 U.S.C. 156. The patent was granted on October 1, 1985, with a terminal disclaimer disclaiming the term of the patent beyond March 13, 2001.

Both the applicable statute (35 U.S.C. 156(d)(1)(D)) and regulation (37 C.F.R. 1.740(a)(11)) require that the application shall contain a brief description of the activities undertaken by the marketing applicant during the regulatory review period with respect to the approved product and the significant dates applicable to such activities. While the content of the application filed on June 27, 1988, is considered to be sufficient to satisfy the statutory requirements for a complete application, there are some gaps in the dates and activities that are described in the application.

The application provides sufficient information to permit the Food and Drug Administration (FDA) to determine the applicable regulatory review period. However, supplementary details would be helpful regarding events occurring between the effective date of the investigational device exemption, and the PMA submission and the approval dates. While the FDA has this information in its possession, FDA regulations generally prohibit its disclosure to the public. Therefore, your assistance is requested in providing additional information about the activities and the associated dates so that interested persons may read the application and exercise their statutory rights under 35 U.S.C. 156(d)(2) in an informed manner.

The supplementary information should be submitted to the Patent and Trademark Office within ONE (1) MONTH of the date of this letter.

C.E. Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent and Trademark Office

Clifford W. Browning
Woodward, Emhardt, Naughton,
Moriarty & McNett
One Indiana Square
Suite 2000
Indianapolis, Indiana 46204

Ronald Wilson
Health Assessmant Policy
Staff
Office of Health Affairs
Food and Drug Admin.
5600 Fishers Lane
Rockville, MD 20857